September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

09 | OPP #34137 A SM

RECEIVED

JUL 29 1998

1088

American Cyanamid Rebuttal to EPA's Health Effects Division (HED) Draft Chapter of the Reregistration Eligibility Decision Document (RED) for Phorate, Case # 0103.

The following is an itemized list of HED's Chemistry Branch Tolerance Support (CBTS II) reregistration concerns as expressed in the Agency memo dated April 16, 1996 from J. Smith, RCAB/HED to J. Bloom, SRB/SRRD followed by American Cyanamid Company's response to those concerns. Toxicology Branch concerns (Points 1-3) are addressed in a separate attachment within this submission.

CBTS Concern (Point 4): "Label amendments are required. The restriction against the feeding of sugar beet tops or silage to dairy cattle is considered impractical and should therefore be removed from labels for EPA Reg. Nos. 241-53, 241-145, and 241-257. In addition, a 30-day pregrazing interval has been established for at-cultivation applications to field corn to control chinch bug nymphs; this pregrazing interval should be extended to the at-cultivation application to field and sweet corn to control corn rootworms (EPA Reg. Nos. 241-53, 241-145, and 241-257)."

Cyanamid Response: The restriction against feeding sugar beet tops or silage to dairy cattle was removed in label notification submissions dated August 5, 1996 for THIMET 20-G soil and systemic insecticide (EPA Reg. No. 241-257) and April 16, 1997 for THIMET 15-G (EPA Reg. No. 241-145). These submissions were partly in response to an EPA letter dated June 16, 1994 which requested that the feeding restriction be removed from THIMET labels. THIMET 10-G (EPA Reg. No. 241-53) is a "dormant" product (i.e., not marketed); however, a label notification submission will be made under separate cover to EPA's Registration Division with the purpose of deleting the feeding restriction language on that product's label.

In addition, label amendment applications will be submitted under separate cover to the Registration Division which will propose that the existing 30-day pre-grazing interval for field and sweet corn at-cultivation uses to control chinch bugs be extended for at-cultivation applications to control corn rootworms.

CBTS Concern (Point 5): "HED concluded that a 12-month plantback restriction was appropriate for root and tuber vegetables, leafy vegetables, and cereal grains. There are currently no rotational crop restrictions on product labels."

Cyanamid Response: EPA's Follow-up Guidance for Conducting Rotational Crop Studies (February, 1993) states "if tolerances exist on the crops to be rotated as a result of a primary use, then rotational data on these crops would be required only if residues in rotated crops are significant in comparison to those in the primary crop." Cyanamid intends to support the existing primary tolerances for phorate-related residues in/on the following crops: beans, coffee, corn, cotton, peanuts, potatoes, grain sorghum, soybeans, sugar beets, sugarcane, sweet corn, and wheat. The following table lists existing primary tolerances along with the total phorate-related residues (i.e., parent compound and regulated cholinesterase-inhibiting metabolites) derived from 9- Month After Treatment (MAT) samples in the initial confined rotational crop study (MRID 42657001, DP Barcode D188792) with representative root (carrots), leafy vegetable (lettuce), small

1

grain (barley) and legume (pea) crops. In the confined rotational study, radio-labeled phorate was applied at a rate of 3.4 lbs ai./A which approximates the maximum labeled rate.

Table 1. Comparison of Crops Holding a "Primary" Tolerance and Residue Levels Found in Representative Crops in a Confined Rotational Study

Raw Agricultural Commodity	RAC Existing Primary Tolerance, (ppm)	Representative Confined Rotational RAC	Maximum Total Phorate-Related Residue Found in Confined Rotational RAC at 9 Months After Treatment, (ppm)
beans	0.1	legume (green seed)	0.014
corn grain	0.1	small grain (grain)	Non-detectable
corn forage	0.5	small grain (plant)	0.31
corn stover	-	small grain (straw)	0.043
cotton seed	0.05	legume (green seed)	0.014
cotton gin trash	-	leafy vegetable	0.027
peanuts	0.1	root crop	0.04
potato	0.5	root crop	0.04
sorghum grain	0.1	small grain (grain)	Non-detectable
sorghum forage	-	small grain (plant)	0.31
sorghum stover	0.1	small grain (straw)	0.043
soybeans	0.1	legume (dried seed)	Non-detectable
sugar beet roots	0.3	root crop	0.04
sugar beet tops	3.0	root crop tops	Non-detectable
sugar cane	0.1	-	-
wheat grain	0.05	small grain (grain)	Non-detectable
wheat forage	1.5	small grain (plant)	0.31
wheat straw	0.05	small grain (straw)	0.043

The regulated phorate-related residue levels in representative crops in the rotational study are insignificant in comparison to the primary tolerances. Thus, based on Agency guidance, no plant back restrictions are necessary for beans, field and sweet corn, cotton, peanuts, potatoes, grain sorghum, soybeans, sugar beets, sugar cane, and wheat.

We also propose no plant-back restrictions for rice as supported by analogous crops holding tolerances in the cereal grain crop grouping including sweet corn, field corn, rice, grain sorghum and wheat. The crop rotation data (Table 1) also support this proposal by demonstrating low to non-detectable residues in the cereal RACs. Based on data from crops in the same crop grouping, significant residues would not be expected in the grain or straw of a rice crop planted following the crops currently on the THIMET label.

In addition, we propose, that the existing tolerances for alfalfa forage and hay be converted to inadvertent residue tolerances at 0.5 ppm and 1 ppm, respectively. The existing primary tolerances are based on data generated from broadcast applications over

(2

the top of the growing plant and therefore represent a worst case scenario. It is highly unlikely that alfalfa planted after a primary crop is treated with THIMET would contain phorate-related residues at higher levels than when alfalfa is treated as a primary crop.

No plant back restriction for tobacco is proposed based on surrogate data from a leafy vegetable (lettuce) in the confined rotational crop study (see Table 1). The lettuce crop in the confined rotational study held 0.027 ppm of total phorate-related residue at the 9 month after treatment sampling. Subdivision O guidelines state that "if total toxic residues $\leq$ 0.1 ppm are found in a tobacco metabolism study, field trial data would not be required." Since the biomass of a mature tobacco plant is much greater than that of a lettuce plant it is reasonable to assume that the potential phorate-related residues in tobacco would be much less than that found in lettuce due to dilution. This assumption is further supported by residue data from cotton foliage collected at 65 days after a planting/ side-dressing treatment of phorate (see Table 5). These data show that total phorate-related residue levels never reach 0.1 ppm when adjusted for rate.

The following rotational crop restriction labeling language is proposed:

> There are no follow crop restrictions for alfalfa, rice, tobacco, and any food/feed crop listed on this label. All other crops require a 12 month plant-back interval from the time of a THIMET soil and systemic insecticide application.

Label text amendments proposing this rotational crop restriction language will be submitted to the Agency under separate cover.

Additionally, the CBRS review of the confined rotational crop data stated that "limited field rotational crop studies with peas must be submitted in order to obtain a plant-back interval." This requirement is based on CBRS' position that a 12 month plant-back interval for peas is deemed unacceptable since unidentified organosoluble extract in pea vines constituted 0.136 ppm and 1.30 ppm for the green, mature pod stage and dried vine stage commodities, respectively. We would like to point out it is well documented from previous plant metabolism studies (including alfalfa, beans, carrots, corn, cotton, lemons, oats and peas) that the phosphorylated cholinesterase inhibiting phorate-related residues (phorate, phoratoxon, and their respective sulfoxides and sulfones) are the compounds of toxicological concern and that these regulated metabolites were non-detectable in pea samples collected at 12 MAT from the confined rotational crop study mentioned above. We therefore propose that a 12 month plant-back interval for peas is reasonable.

CBTS Concern (Point 6): "No tolerances currently exist for field corn stover (fodder), sweet corn stover (fodder), sorghum forage, and wheat hay. Some field residue data have been submitted for these commodities; however, none of the available data reflect the currently registered use patterns for these crops. Therefore, additional field residue data are required for these commodities. In addition, Table II (in Subdivision O of the Pesticide Assessment Guidelines September, 1995) identifies cotton gin byproducts as a

raw agricultural commodity of cotton; therefore, field residue data must be submitted for cotton gin byproducts. Tolerances must be proposed for these commodities when adequate field residue data have been submitted."

Cyanamid Response: Field and sweet corn stover.

As per Table 1 of Subdivision O - Pesticide Assessment Guidelines, field and sweet corn stover (fodder) is considered "mature [emphasis added] dried stalks from which the grain or whole ear (cob + grain) have been removed; containing 80 to 85 percent [dry matter]." The Subdivision O guideline also says that field and sweet corn forage (still green, living plant tissue) ranges from 40-48 percent dry matter. The following data in Table 2 on corn forage show apparent phorate-related residues (corrected for rate) in green field corn or sweet corn plants collected from plots with long pre-harvest intervals (i.e., closer to maturity). By definition, green plant forage harvested closer to maturity is closer to the dried-down stover stage and therefore represents worst case surrogate data for stover.

Stover would typically be harvested after the field corn grain or sweet corn cob RACs are harvested and the remaining plant material is dried down. Although potential residues are expected to further dissipate in stover versus forage due to additional length of time to harvest, we acknowledge that the drying process itself can concentrate those potential residues. By using residue values derived from forage without accounting for further dissipation with time, a conservative estimate of the potential phorate-related residues in field and sweet corn stover is listed in the last column in the table above. The data in Table 2 show that when forage (i.e., green plant) data are corrected for percent dry matter to calculate conservative estimates of residue values in stover (dried plant), the estimated values fall within the existing 0.5 ppm tolerance level for forage.

The equation used to calculate estimated phorate-related residue values in corn stover is as follows:

$$\frac{\text{(forage residue level x 83\% D.M. in stover)}}{\text{(\% D.M. in forage)}} = \text{estimated stover residue level}$$

Note: % Dry Matter (D.M.) is estimated from Subdivision O, Table 1.

Additionally, Subdivision O states that the percentage of corn stover in beef or dairy cattle diets is 25% or less. Since this dietary percentage value is less than that for forage in beef or dairy cattle (≤ 50%) and since results of an animal feeding study led the Agency to conclude that tolerances are not required for bovine meat, milk, and meat by products, there is no reasonable expectation that stover residues would transfer to meat or milk products. Subsequently, the establishment of a tolerance for corn stover will not contribute to the dietary risk for phorate.

Thus, Cyanamid contends that additional residue studies to generate field and sweet corn stover data are not needed and that a 0.5 ppm tolerance for phorate-related residues in stover can be proposed based on existing forage data.

Table 2. Predicted Stover Phorate-Related Residue Levels Derived From Field and Sweet Corn Forage Residue Data

MRID / Study Number	RAC Description	Total Applied Rate (lb ai/A); At planting + At cultivation.	Days After Treatment	Apparent phorate-related residues (ppm) corrected for application rate	Predicted phorate related residues (ppm) in corn stover (corrected for 83% dry matter)
MRID 00158330 60934-85-T10B	field corn forage with 40% dry matter	1.3 + 1.3 (1X rate)	106	<0.05	<0.10
		"	121	<0.025	<0.05
		2.6 + 2.6 (2X rate)	106	0.065	0.13
		"	121	<0.025	<0.05
MRID 00158330 60934-85-T10C		1.3 + 1.3	107	<0.05	<0.10
		"	122	<0.05	<0.10
		2.6 + 2.6	107	<0.025	<0.05
		"	122	<0.025	<0.05
MRID 00160047 60936-85-T12D	sweet corn forage with 48% dry matter	1.3 + 1.3 (1X rate)	74	<0.05	<0.09
		2.6 + 2.6 (2X rate)	74	<0.025	<0.04
		6.5 + 6.5 (5X rate)	74	<0.01	<0.02
MRID 00160047 60928-85-P33		1.3 (at planting) (1/2X rate)	71	0.30	0.52
MRID 00160047 60910-85-T12E		2.6	57	0.05	0.09
		5.2	57	0.055	0.095

Grain sorghum forage.

Subdivision O defines grain sorghum forage as the whole aerial portion of the plant at the soft dough to hard dough stage of the grain. The following residue study data in Table 3 show that existing results can indeed be used to support a tolerance for sorghum forage, especially in light of the current sorghum fodder (stover) tolerance and the fact that residues are typically concentrated in dried plant material such as fodder.

These data represent a worst case scenario with regard to potential phorate residues in sorghum forage since the second treatment was applied (in some instances at exaggerated rates) directly over the top of the sorghum foliage at 30 to 46 days before the plants were harvested. The results show that potential phorate-related residues from this treatment regime were all below the 0.05 ppm analytical level of quantitation established for sorghum green plant material. It is unreasonable to suspect that at cultivation applications of phorate to the soil at the approved label rate of 1.3 lbs a.i./A would result in higher potential residues than those derived from the foliar application described above. Therefore we propose that a tolerance be established for sorghum forage at 0.1 ppm based on the existing data. This tolerance level would be similar to that already established for sorghum fodder (stover) and will not contribute to the overall dietary risk.

Table 3. Phorate-related Residues in Grain Sorghum Plants, MRID 40174520.

Study Number	Description of Sorghum Plant RAC at Harvest	Applied Rate (lb ai/A); [At planting + foliar]	Days After Last Treatment	Apparent phorate-related residues (ppm) corrected for application rate
60929-85-T14A	soft dough stage	1.3 + 1.0 (or 1.8X rate)	30	<0.03
			45	<0.03
		2.6 + 2.0 (or 3.5X rate)	30	<0.014
			45	<0.014
60929-85-T14B	hard dough stage	1.3 + 1.0	30	<0.03
			44	<0.03
		2.6 + 2.0	30	0.05
			44	<0.014
60933-85-T14C	90-100 days after planting	1.3 + 1.0	30	<0.03
			46	<0.03
		2.6 + 2.0	30	<0.014
			46	0.017
60933-85-T14D	90-100 days after planting	1.3 + 1.0	30	<0.03
			46	<0.03
		2.6 + 2.0	30	<0.014
			46	<0.014

Wheat hay

Subdivision O defines wheat hay as the plant cut at early flower to soft dough stage. The following residue study data in Table 4 show that existing results can indeed be used to support a tolerance for wheat hay, especially in light of the current wheat forage tolerance and the fact that residues are typically concentrated in dried plant material such as hay.

These data represent a worst case scenario with regard to potential phorate residues in wheat hay since the aerial treatment was applied (in some instances at exaggerated 2X rates) directly over the top of the wheat plants at 30 to 59 days before the plants were harvested. The results show that potential phorate-related residues from this treatment regime were all below the current wheat forage tolerance of 1.5 ppm. It is unreasonable to suspect that at planting applications of phorate to the soil at the approved label rate of 0.98 lbs a.i./A would result in higher potential residues than those derived from the aerial applications described above. Therefore we propose that a tolerance be established for wheat hay at 1.5 ppm based on the existing data. This tolerance level would be similar to that already established for wheat forage with a PHI of 70 days.

Table 4. Predicted Wheat Hay Phorate-Related Residue Levels for Ground Applications Derived From Aerial Applications

MRID / Study Number	RAC Description	Total Applied Rate (lb ai/A); At planting	Days After Treatment	Apparent phorate-related residues (ppm) corrected for application rate
MRID 00160048 60929-85-T16N	Hay Aerial Application	1	39	0.06
	Hay		41	0.09
	Hay		45	0.09
	Hay		52	0.06
	Hay		59	0.06
	Hay	2 (2x rate)	39	0.14
	Hay		41	0.19
	Hay		45	0.18
	Hay		52	0.05
	Hay		59	0.09
MRID 00160048 60936-85-T16B	Hay Aerial Application	1	30	0.12
	Hay		32	0.24
			36	0.1
			43	0.15
			50	0.12
	Straw		70	<0.05
	Hay	2 (2X rate)	30	0.17
			32	0.12
			36	0.17
			43	0.13
			50	0.1
	Straw		70	<0.025

Additionally, Subdivision O states that the percentage of wheat hay in beef or dairy cattle diets is 25% and 60%, respectively. Since this dietary percentage value is less than that for forage in beef or dairy cattle 30% and 65%, respectively and since results of an animal feeding study led the Agency to conclude that tolerances are not required for bovine meat, milk, and meat by products, there is no reasonable expectation that hay residues would transfer to meat or milk products.

As these data do not contribute to the dietary risk assessment of phorate we suggest sufficient data are available to set a conservative tolerance of 1.5 ppm in wheat hay.

Cotton Gin By-Products

Subdivision O defines cotton gin by-products, (commonly called gin trash) as the plant residues from ginning cotton, and consists of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt. The following residue study data in Table 5 show that existing results can indeed be used to support a tolerance for cotton gin by-products, especially in light of the fact that cotton plant foliage, mature cotton plants, mature dry cotton plants

6

and seed residue data are all represented and simulate cotton gin by-products which are essentially made up of the same parts (burrs, leaves, stems, lint, and seeds) as gin trash except that it was not put through a cotton gin. It should be noted that the residue data presented here has two applications of THIMET applied, one at planting and one as a side dress application. In fact, over 95% of the THIMET sold on cotton is applied in an at planting application thus the residue data here illustrate extremely exaggerated rates as side dressed applications were made in all but one trial.

Additionally, Subdivision O states that the percentage of cotton gin by-products in beef and dairy cattle diets is 20%, therefore any residues present in the cotton gin by-products would be diluted 5-fold. Since results of an animal feeding study led the Agency to conclude that tolerances are not required for bovine meat, milk, and meat by products, there is no reasonable expectation that cotton gin by-product residues would transfer to meat or milk products.

As these potential residues do not contribute to the dietary risk assessment of phorate, we suggest sufficient data is available to set a conservative tolerance of 2 ppm in cotton gin by products.

Table 5. Predicted Cotton Gin By Products Phorate-Related Residue Levels from Cotton Plant, Dry Plant and Seed Residue Data

MRID / Study Number	RAC Description	Total Applied Rate (lb ai/A); At planting plus side dressed[1]	Days After Treatment	Apparent phorate-related residues (ppm) corrected for application rate
MRID 40174521	plant foliage	1.5 + 2.2 (1X rate)	65	<0.05
60927-85-T18F	seed	"	65	<0.05
	seed	2.2 + 4.4 (1.8X rate)	65	<0.05
	plant foliage	3.2 + 4.4 (2X rate)	65	0.11
	seed	"	65	<0.025
	seed	6.4 + 8.8 (4X rate)	65	<0.01
MRID 40174521	dry whole mature plant	1.6 + 2.2 (1X rate)	64	0.16
60929-85-T16E	seed	"	64	<0.05
	dry whole mature plant	3.2 + 4.4 (2X rate)	64	0.25
	seed	"	64	<0.05
MRID 40174521	seed	1.6 + 2.2 (1X rate)	120	<0.05
60903-85-T16B	seed	3.2 + 4.4 (2X rate)	120	<0.025
MRID 40174521	cotton plants at harvest	0.75	137	<0.05
60909-85-T18G	seed	"	137	<0.05
	cotton plants at harvest	1.6 + 2.2 (1X rate)	90	<0.05
	seed	"	90	<0.05
	cotton plants at harvest	3.2 + 4.4 (2X rate)	90	<0.025
	seed	"	90	<0.025
MRID 40174521	cotton plants at harvest	1.6 + 3.2 (1.3X rate)	61	1.3
60904-85-T18G	seed	"	61	<0.04
	cotton plants at harvest	2.2 + 4.4 (1.7X rate)	61	1.9
	seed	"	61	<0.029
	seed	2.2 + 4.4 (1.7X rate)	61	<0.029
	seed	6.4 + 8.8 (4X rate)	61	<0.0125

[1]Less than 5% of the THIMET applied to cotton is applied in a side dress application.

CBTS Concern (Point 7): "NO field residue data are available to support the use of phorate on field corn under SLNs)R840038 and WA840041 (broadcast aerial application prior to tassel emergence). The registrant for these SLNs is Platte Chemical Company. American Cyanamid does not wish to support this use pattern and SLNs registered to American Cyanamid with this use pattern were canceled by the registrant in response to data requirements imposed in the FRSTR. Unless Platte Chemical Company wishes to submit field residue data to support these use patterns, SLNs OR840038 and WA840041 should be canceled."

Cyanamid Response: American Cyanamid Company reiterates that it does not support the aerial use of phorate.

CBTS Concern (Point 8): "The greenhouse/nursery uses are not included in this assessment, since there are no such uses registered."

Cyanamid Response: We concur.